

REMARKS

The Examiner has rejected claims 1-42 under 35 U.S.C. § 112. Claims 1-2, 9-10, 17-34 & 37-42 stand rejected under 35 U.S.C. § 102(e) in light of the disclosure of Banner et al (U.S. Patent No. 6,390,091). Claims 3-8, 11-16, and 35-36 stand rejected under 35 U.S.C. § 103(a) over Banner et al. (U.S. Patent No. 6,390,091) in view of Schmidt (U.S. Patent No. 6,186,142). For the following reasons, Applicant requests that the Examiner withdraw the rejections and allow claims 1-48 as amended herein.

A. Rejections under 35 U.S.C. § 112, First and Second Paragraph

With regard to claims 1-42, the Examiner contends that the phrase “respiratory phase” defines specific stages of the respiratory cycle of a patient and as such it is repugnant in a dependent claim to further define this phrase to be a fraction of a respiratory cycle. Applicant disagrees that those skilled in the art would view the language in such a limited way. Nevertheless, the Applicant has amended claims 1, 17, 33 and 37 to remove the phrase for the purpose of expediting the application process in a manner consistent with the PTO’s Patent Business Goals (PBG), 65 Fed. Reg. 54603 (Sept. 8, 2000). Accordingly, Applicant submits that the language of the claims complies with 35 U.S.C. § 112.

B. Rejections under 35 U.S.C. § 102

An invention is anticipated under § 102 if the same device, including all the claim limitations, is shown in a single prior art reference. *Richardson v. Suzuki Motor Co. Ltd.* 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989). Every element of the claimed invention must be literally present, arranged as in the claim. *Perkin-Elmer Corp v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir.), *cert. denied*, 469 U.S. 857 [225 USPQ 792] (1984); *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771-72, 218 USPQ 781, 789 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 [224 USPQ 520] (1984). The identical invention must be shown in as complete detail as is contained in the patent claim. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 756 F.2d 1556,1560, 225 USPQ 253, 256 (Fed. Cir. 1985); *Connell v. Sears, Roebuck & Co*, 722 F.2d 1542, 1548, 220 USPQ 193,198 (Fed. Cir. 1983).

1. Claims 1-42

The Examiner contends that Banner et al. (U.S. 6,390,091) anticipates the invention of claims 1-2, 9-10, 17-34 and 37-42. However, Applicant submits that an important feature defined by the independent claims 1, 17, 33 and 37 of the application is not literally or inherently

present in the device of Banner et al. To this end, the present claims define methods and apparatus that include a determination of at least one instantaneous phase of respiration or a respiratory cycle from both respiratory airflow and respiratory effort. The patent to Banner et al. does not disclose a methodology with such a determination or an apparatus configured to perform this methodology.

To this end, in the last Office Action, the Examiner adopted the view that the patent to Banner et al. discloses a determination of respiration phase based upon both airflow and effort since the level of pressure support ventilation is disclosed as being set by a work of breathing formula. March 17, 2003 Office Action at 9. While Applicant agrees that the pressure support level is adjusted based on a work of breathing formula as defined by Banner et al. (col. 21, line 7 and col. 24, line 44), Applicant submits that Banner et al. do not disclose synchronization ((a) triggering -initiation of the pressure support ventilation level at the onset of patient inhalation or (b) cycling - the termination of the pressure support ventilation level at the end of inhalation) based on this work of breathing formula. While Banner discloses that the pressure support ventilation level of the ventilator is increased or decreased if the calculated work of breathing is not within a preset range of work of breathing, these disclosed changes are described as adjusting the "selected pressure support level." Banner et al, col. 19, lines 49-62. However, Banner et al. define that their "pressure support ventilation" apparatus does not change the pressure support level during inhalation as only one constant level is delivered. Banner states "as long as the patient maintains an inspiratory effort, airway pressure is held constant at the preselected pressure support ventilation level." Banner, col. 8, lines 47-49. Thus, the application of any changes to the level of the delivered pressure support ventilation of Banner et al.'s apparatus based on the work of breathing methodology must only occur after inhalation ceases in the next breath. Thus, the "preselected" adjustments to the pressure support level by the work of breathing formula that includes flow and pressure effort variables cannot be interpreted as a determination of at least one instantaneous phase of respiration or a respiratory cycle from both respiratory airflow and respiratory effort because they do not participate in synchronization.

In discussing the first embodiment of the pressure support ventilator they created, Banner et al. describe how synchronization is achieved. Banner et al. state:

In pressure support ventilation, the ventilator 20 is patient-triggered "ON," resulting in an abrupt increase in pressure within the endotracheal tube 54 to the preselected pressure support ventilation level, which provides a positive-pressure

level, resulting from a variable flow of gas 32 from the ventilator 20. As long as the patient 10 maintains an inspiratory effort, airway pressure is held constant at the preselected pressure support ventilation level. Gas flow rate from the ventilator 20 typically ceases when the patient's inspiratory flow rate demand decreases to a predetermined percentage of the initial peak mechanical inspiratory flow rate (e.g., 25%). The ventilator 20 is thus flow-cycled "OFF" during pressure support ventilation.

Banner et al., col. 8, lines 42-54 (emphasis added). Given this express disclosure, it is clear that Banner et al. teaches triggering based on patient "effort", not work, and cycling based on flow. As the Examiner concedes, effort is commonly measured by pressure. Office Action at 9.

Similarly, with regard to the use of the work of breathing formula to adjust the pressure support level in a work-modified second embodiment of a ventilator apparatus¹, Banner et al. describe that the device is the same as the first device with the one exception of the use of an endotracheal tube in the patient's airway. Banner et al. describe:

[T]he only significant difference, as would be apparent to one skilled in the art, is that the pressure sensor 100 of the first embodiment must be disposed proximate the distal end of the endotracheal tube 54.

Banner et al., col. 31, lines 3-9. As such, Banner et al. does not disclose a device which determines at least one instantaneous phase of respiration or a respiratory cycle from both respiratory airflow and respiratory effort. In short, the formula for determining work of breathing which includes flow and pressure based effort variables in either embodiment of the apparatus of Banner et al. does not participate in synchronization or determining phase as claimed in the independent claims of the application.

Accordingly, as all of the independent claims of the application (1, 17, 33 and 37) define a limitation not present in the reference, Applicant submits that all of the claims of the application are in condition for allowance.

2. New Method claims 47 and 48

With regard to the invention of new method claims 47 and 48, Banner et al. do not control synchronization based upon a detection of respiratory effort from a leak independent effort sensor positioned out of the patient-ventilator airway circuit. The tracheal pressure detection device of Banner et al. is not a device for the detection of

¹ The unmodified second embodiment of the apparatus disclosed by Banner et al. is not based upon a work of breathing formula. This apparatus synchronizes changes only by monitoring changes in pressure. Banner et al. col. 29, lines 26-67.

respiratory effort that is immune from errors associated with leak as it is positioned in the airway of the patient. The pressure-sensing device of Banner et al. being in the trachea portion of the patient's airway may still be subject to errors in the presence of a leak. For this reason, respiratory effort detection devices outside the airway circuit are considered more accurate.

Thus, claim 47 includes the positively recited step of positioning the effort sensor to sense patient effort external to the patient-ventilator airway circuit in a manner that is independent from leak in the patient-ventilator airway circuit. Claim 48 includes the positively recited step of locating an effort sensor in a manner to render the sensor independent of leak in the patient-ventilator circuit. Banner et al. does not disclose such steps. Rather, Banner et al. implement use of a device that is within the patient-ventilator circuit and which is subjected to the effects of leak in such a system. Thus, claims 47 and 48 define novel and non-obvious subject matter not disclosed in Banner et al.

2. Claims 2, 18, 34 and 38

Similarly, as noted in the current specification, the effort sensors that are chosen for the Applicant's ventilator apparatus are immune to errors associated with leak in airflow measurement. Specification, p. 4, line 35 - p. 5, line 1. Thus, claims 2, 18, 34 and 38 each define effort sensors that are leak independent. While Examiner asserts that this phraseology forms part of the claim preamble, Applicant submits that the "wherein" clause of these claims is a positively defined limitation. As claimed, Banner et al. does not disclose either a suprasternal notch sensor, an esophageal pressure effort sensor or an electromyograph. Rather, element 100 from Fig. 10 of Banner et al. is endotracheal pressure sensor. Banner et al. states that "the preferred pressure sensor 100 may be comprised of a disposable endotracheal tube provided by Mallinckrodt Critical Care having a pressure sensor 100 embedded within a lumen in the sidewall of the endotracheal tube 54 near the distal end 56 of the endotracheal tube 54." Banner et al., col. 29, lines 10. Applicant notes that Banner et al. also do not disclose an esophageal effort sensor. There is an important distinction between the esophagus as part of the digestive system and the trachea as part of the patient's airway. The preferred device of Banner et al. includes a particular "endotracheal tube" inserted into the patient's mouth and into the patient's trachea so that the distal end of the endotracheal tube is disposed in the trachea before it branches into the mainstream bronchi that leads to the patient's lung. Applicant submits that those skilled in the art would recognize the existence of a structural difference

between such a tracheal effort sensor and an esophageal effort sensor.

Accordingly, Applicant submits that claims 2, 18, 34 and 38 define novel and non-obvious subject matter and are in condition for allowance.

Claims 33-36 and 37-40 and 41-42

With regard to amended independent method claims 33 and 37 and respective dependent claims 34-36 and 38-40 and claims 41 and 42, applicant has made clear that the phase determined by both the respiratory airflow and respiratory effort is a fraction of a revolution. This feature is not disclosed in the patents to Banner et al. or Schmidt et al. While the examiner has taken the position that this limitation is a use or result not positively claimed, Applicant requests that the Examiner reconsider. As this limitation relates to the method claims of 33-36 and 41, the language defines how the recited step is to be accomplished, a clear manipulative difference not present in the prior art. Similarly, with regard to apparatus claims 37-40 and 42, the claims define the processor configured to perform the claimed step of determining phase as a fraction of a revolution. Those skilled in the art would recognize that such a configuration presents a structural difference when compared to the prior art.

Accordingly, Applicant submits that these claims are in condition for allowance.

Claims 19-24, 27-32 and 39-40

Similarly, Applicant requests that the Examiner reconsider the rejection of apparatus claims 19-24, 27-32 and 39-40 which was previously based on the conclusion that the language therein was not positively recited. Applicant submits that these claims as amended positively recite a processor configured to perform the functions/steps recited. For example, amended claims 19 and 39 clearly state that the processor is configured to control an evaluation of fuzzy inference rules. Claims 20-24, 27-32 and 39-40 further limit this structure by defining the configuration of these fuzzy inference rules. Applicant submits that these limitations are positively recited. Those skilled in the art would recognize that such a configuration presents a structural difference when compared to the prior art.

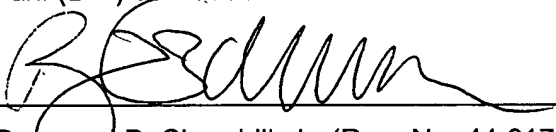
For these reasons, Applicant requests that the Examiner withdraw the rejection of these claims.

D. Rejections under 35 U.S.C. § 103

For the reasons stated above with regard to the independent claims of the application, Banner et al. does not disclose determining at least one instantaneous phase from both respiratory airflow and respiratory effort as well as the remaining limitations discussed above.

Similarly, the patent to Schmidt et al. does not disclose or suggest such limitations. Notably, Schmidt et al. does not disclose determining at least one instantaneous phase based upon an analysis of both respiratory airflow and respiratory effort. Schmidt et al. only disclose a flow triggering respiration sensor. Schmidt et al., col. 9, line 28 - col. 10, line 9. Moreover, in light of Banner et al.'s statements to the effect of the "inherent inadequacy" of flow based triggering, Banner et al., col. 28, line 34, there can not be said to be a suggestion to combine the references because Banner et al. teach away from the use of flow based triggering. When the prior art can be said to teach away from an invention, there cannot be said to be a motivation, suggestion or teaching to combine the references. *Tec Air Inc. v. Denso Manufacturing Michigan Inc.*, 192 F.3d 1353, 1360 (Fed. Cir. 1999). Accordingly, Applicant submits that the defined inventions of claims 1-48 are not obvious.

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9/26/2003
Date